

WHAT IS CLAIMED IS:

1. A method for inserting an article in a body opening, comprising:
dilating the body opening;
inserting a radially expandable introducer sheath into the dilated body
5 opening;
radially expanding the introducer sheath to enlarge said body opening by
inserting the article through said expandable introducer sheath; and
removing said introducer sheath while leaving the article in place in said body
opening.
- 10 2. The method of claim 1, wherein the radially expandable introducer
sheath comprises a handle and a sheath body, said handle having a perimetrical
opening.
3. The method of claim 2, wherein said sheath body comprises a member
selected from the group consisting of expanded polytetrafluoroethylene, polyethylene
15 terephthalate, polytetrafluoroethylene and nylon.
4. The method of claim 3, wherein the handle is generally C-shaped and
comprises a circumferential opening, and the sheath body comprises expanded
polytetrafluoroethylene.
5. The method of claim 2, wherein the handle comprises a pivotable
20 portion and a disengageable portion, the handle being selectively maneuverable
between a closed position wherein said handle has a substantially continuous outer
surface, and an open position wherein said pivotable portion is pivoted and said
disengageable portion disengages such that an opening is defined for permitting
withdrawal therethrough of said introducer sheath.
- 25 6. The method of claim 1, wherein the radially expandable introducer
sheath comprises a release mechanism for allowing radial expansion of said sheath
from a non-expanded condition to an expanded condition.
7. The method of claim 6, wherein the release mechanism comprises an
insertion cannula, said insertion cannula positioned such that a distal end of said
30 introducer sheath is maintained within said insertion cannula to retain the introducer
sheath in the non-expanded condition.
8. A method for percutaneously inserting an article in a body opening,
comprising:
inserting a wire guide into the body opening;

dilating the body opening by inserting a dilator over said wire guide, the dilator mechanism including an outer cannula having a lumen therethrough and a dilator within said lumen;

withdrawing the dilator while leaving the outer cannula in said body opening;

5 delivering a radially expandable introducer sheath over the wire guide into the lumen of said outer cannula, said introducer sheath being delivered in a non-expanded condition and comprising a release mechanism for releasing the introducer sheath from the non-expanded condition;

removing the outer cannula, leaving the introducer sheath in the body opening;

10 activating the release mechanism to permit radial expansion of said introducer sheath; and

inserting the article through the expandable introducer sheath, thereby radially expanding the sheath.

9. The method of claim 8, wherein the outer cannula comprises a peel-
15 away sheath, and wherein said outer cannula is removed by peeling away the sheath.

10. The method of claim 8, wherein said dilator and outer cannula comprise a common distal taper for dilating said body opening.

11. The method of claim 8, wherein the release mechanism comprises an insertion cannula, said insertion cannula positioned such that the distal end of said
20 introducer sheath is maintained between said insertion cannula and said wire guide to retain the introducer sheath in the non-expanded condition, and wherein said release mechanism is activated by releasing said introducer sheath distal end from said maintained condition.

12. The method of claim 11, wherein the release mechanism further
25 comprises a pusher mechanism for pushing said distal end from said maintained condition, thereby activating said release mechanism.

13. The method of claim 12, wherein the release mechanism further comprises a dilator tip.

14. The method of claim 8, wherein the introducer sheath comprises a
30 sheath body and a handle.

15. The method of claim 14, wherein the handle comprises a perimetrical opening, and wherein the method further comprises the step of removing the introducer sheath by withdrawing the sheath from the inserted article through the perimetrical opening while leaving the article in place in said body opening.

16. The method of claim 15, wherein the handle is generally C-shaped and comprises a circumferential opening.

17. The method of claim 14, wherein the sheath body comprises a low friction non-rigid material.

5 18. The method of claim 17, wherein the sheath body comprises a hydrophilic coating.

19. The method of claim 14, wherein the sheath body comprises a member selected from the group consisting of expanded polytetrafluoroethylene, polyethylene terephthalate, polytetrafluoroethylene and nylon.

10 20. The method of claim 19, wherein the sheath body comprises expanded polytetrafluoroethylene.

21. The method of claim 15, wherein the sheath body comprises an axial slit extending substantially along the length of the sheath body, and wherein said introducer sheath is removed by splitting the sheath body along said axial slit and
15 withdrawing the sheath from the inserted article at said split.

22. The method of claim 21, wherein the sheath body comprises a knick for initiating said splitting of the sheath body.

23. The method of claim 14, wherein the sheath body includes lateral folds when in the non-expanded condition.

20 24. The method of claim 14, wherein the handle comprises one or more finger supports.

25. The method of claim 17, wherein the sheath body comprises an axial slit extending substantially along the length of the sheath body.

26. The method of claim 14, wherein the handle has a continuous
25 perimetrical surface.

27. The method of claim 14, wherein the handle comprises a pivotable portion and a disengageable portion, said handle being selectively maneuverable between a closed position wherein said handle has a substantially continuous outer surface, and an open position wherein said pivotable portion is pivoted and said
30 disengageable portion disengages such that an opening is defined for permitting withdrawal of said introducer sheath from said inserted article.

28. The method of claim 8, wherein the radially expandable introducer sheath comprises a hemostatic valve.

29. A radially expandable introducer sheath for enlarging a percutaneous opening, comprising:

a sheath body, said sheath body having a distal end comprising a folded portion when said sheath is in a non-expanded condition and an extended portion when

5 said sheath is in a radially expanded condition; and

an insertion member for holding said sheath body in said non-expanded condition.

30. The radially expandable introducer sheath of claim 29, further comprising a handle engaged with said sheath body.

10 31. The radially expandable introducer sheath of claim 30, wherein said insertion member is a cannula having an inner lumen, and said folded portion is folded within said inner lumen, further comprising a pusher member for pushing said folded portion from said inner lumen to permit radial expansion of the introducer sheath.

15 32. The radially expandable introducer sheath of claim 30, wherein said handle comprises a perimetrical opening.

33. The radially expandable introducer sheath of claim 30, wherein the handle is generally C-shaped and comprises a circumferential opening.

34. The radially expandable introducer sheath of claim 30, wherein the sheath body comprises a low friction non-rigid material.

20 35. The radially expandable introducer sheath of claim 29, wherein the sheath body comprises a member selected from the group consisting of expanded polytetrafluoroethylene, polyethylene terephthalate, polytetrafluoroethylene and nylon.

36. The method of claim 35, wherein the sheath body comprises expanded polytetrafluoroethylene.

25 37. The radially expandable introducer sheath of claim 30, wherein said sheath body comprises an axial slit extending substantially along the length of the sheath body.

38. The radially expandable introducer sheath of claim 34, wherein the handle comprises one or more ring members for engaging said sheath body to said
30 handle.

39. The radially expandable introducer sheath of claim 29, further comprising a hemostatic valve member.

40. The radially expandable introducer sheath of claim 30, wherein the handle comprises a pivotable portion and a disengageable portion, said handle being

selectively maneuverable between a closed position wherein said handle has a substantially continuous outer surface, and an open position wherein said pivotable portion is pivoted and said disengageable portion disengages such that an opening is defined for permitting withdrawal of said introducer sheath from said inserted article.

5 41. A radially expandable introducer sheath for use in the percutaneous insertion of an article in a body opening, comprising:

 a sheath body alignable to provide an axial opening for passage of said article therethrough into said body opening; and

 a handle engaged with said sheath body, said handle comprising an axial
10 opening aligned with said sheath body axial opening for passage of said article therethrough, said handle further comprising a perimetrical opening for removal of the sheath from the inserted article in the body opening.

 42. The radially expandable introducer sheath of claim 41, wherein the handle is generally C-shaped and comprises a circumferential opening.

15 43. The radially expandable introducer sheath of claim 41, wherein the sheath body comprises a low friction non-rigid material.

 44. The radially expandable introducer sheath of claim 43, wherein the sheath body comprises expanded polytetrafluoroethylene.

 45. The radially expandable introducer sheath of claim 44, further
20 comprising a hemostatic valve member.

 46. An introducer sheath system for use in the percutaneous insertion of an article in a body opening, comprising:

 an introducer sheath comprising a sheath body and an insertion cannula, a distal end of said sheath body being foldable within an inner lumen of said insertion
25 cannula when said sheath is in a non-expanded condition, and extendable beyond said insertion cannula to permit radial expansion of said sheath; and

 a dilator for dilating the body opening.

 47. The introducer sheath system of claim 46, further comprising a sheath member for said dilator, wherein said sheath member provides a passageway for said
30 introducer sheath into the body opening.

 48. The introducer sheath system of claim 46, further comprising a pusher mechanism for pushing said sheath body distal end from said non-expanded condition to permit radial expansion of said sheath.

49. The introducer sheath system of claim 46, further comprising a pusher mechanism and a cap, said insertion cannula, pusher mechanism and cap comprising an assembly releasable as a unit from said system following radial expansion of said sheath.

5 50. The introducer sheath system of claim 46, further comprising a handle engaged with said sheath body.

51. The introducer sheath system of claim 50, wherein said handle comprises a perimetrical opening.

52. The introducer sheath system of claim 50, wherein the handle is
10 generally C-shaped and comprises a circumferential opening.

53. The introducer sheath system of claim 50, wherein the handle comprises a pivotable portion and a disengageable portion, said handle being selectively maneuverable between a closed position wherein said handle has a substantially continuous outer surface, and an open position wherein said pivotable
15 portion is pivoted and said disengageable portion disengages such that an opening is defined for permitting withdrawal of said introducer sheath from said inserted article.